DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

5/398d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-03

October 16, 2003

Brian D. Leaghty, President
Ortho Technology, Inc.
17401 Commerce Park Boulevard
Tampa, Florida 33647

Dear Mr. Leaghty:

During an inspection of your establishment located in Tampa, Florida on July 8-14, 2003, Investigator Bill Tackett, Jr. determined that your establishment is a repackager/relabeler and a specification developer for various orthodontic appliances. These products are intended for use in orthodontic treatment so that pressure can be exerted on the teeth and are devices, as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act)[21 U.S.C.§321(h)].

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h)[21 U.S.C. §351(h)] of the Act.

Specifically, the investigator noted the following violations:

1. Management with executive responsibility has failed to establish adequate policies and objectives for an effective quality system that is fully implemented and maintained at all levels of the organization as required by 21 CFR 820.20. Several repeat observations from the previous inspection were made including: failure to complete device history records (DHR) and device master records (DMR) and document acceptance activities [FDA 483, Item #9].

2. Your firm failed to establish and maintain complete corrective and preventative action (CAPA) procedures to analyze appropriate sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems as required by 21 CFR 820.100(a) & (b). Your firm failed to

investigate and document Supplier Corrective Action Requests (SCARS), complaints and other sources of quality data to the root cause. SCARS and complaints were closed and no corrective and/or preventive action was determined to address the non-conformities [FDA 483, Item #s 2, 3, 4, & 5].

3. Your firm failed to establish and maintain complete procedures and requirements for the acceptance and rejection of incoming product as required by 21 CFR 820.80(b). The investigator determined that incoming inspection procedures requiring 100% inspection of the Equa Pull devices have not been established or maintained and there is no test equipment on hand to accurately determine the pull-force accuracy of the device [FDA 483, Item #1 & 6].

4. Your firm failed to evaluate and select potential suppliers on the basis of their ability to meet specified requirements, including quality requirements with all evaluations documented as required by 21 CFR 820.50(a)(1). You failed to document supplier audits and your audit procedure (PUR-0200) fails to describe supplier audit procedures [FDA 483, Item #7].

5. Your firm failed to establish and maintain complete acceptance records that demonstrate the device is manufactured in accordance with the DMR as required by 21 CFR 820.184(d). The investigator determined that your firm failed to document dates of manufacture, quantity released and acceptance requirements. [FDA 483, Item #8].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Your firm's response dated August 6, 2003 signed by Shelley Forcke, Quality Assurance, is inadequate because it fails to provide any specific evidence or documentation of corrective actions made; the response only promises that future actions will be taken.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District